



**CLARIS LIFESCIENCES LIMITED AUDITED FINANCIAL RESULTS FOR THE QUARTER AND FINANCIAL YEAR (FIFTEEN MONTHS) ENDED 31<sup>st</sup> MARCH 2015**

Ahmedabad, India, 22<sup>nd</sup> May 2015: Claris Lifesciences Ltd. (CLL) today announced its Audited Financial Results for the quarter and financial year (fifteen months) ended 31<sup>st</sup> March 2015 at its board meeting held at its registered office in Ahmedabad.

**Management Representation of the Financial of the Speciality Injectable Business:**

*(Values in Rupees Mn)*

Particulars	Q1CY15	Q1CY14	Growth
Net Sales	1,117	723	54%
EBITDA	404	223	81%
EBITDA Margin (%age)	36%	31%	

**Key financial highlights of the Specialty Injectable Business:**

- Net Sales for Q1CY15 stood at Rs. 1117 mn, which has grown by approximately 54% as compared to the management estimates of the same quarter in the previous year.
- EBITDA has grown by 81% over the same quarter previous year.
- EBITDA margins for the quarter stood at 36%, higher by 500 bps compared to the same quarter previous year.

**Region wise Net Sales**

*(Values in Rupees Mn)*

Region	Q1CY15	Q1CY14	Growth
USA	503	93	441%
Other Regulated (Ex US)	248	195	27%
Emerging Markets	366	435	-16%
<b>TOTAL</b>	<b>1,117</b>	<b>723</b>	<b>54%</b>

- United States continues to be the key growth driver, with sales having grown by 441% as compared to the same quarter previous year.
- Further, the company is building its team with experience professionals in the US in line with the expected requirements of the growing sales.

**Key financial highlights of the consolidated financials of Claris Lifesciences Ltd.:**

The Infusion business for Emerging Markets was transferred to Claris Otsuka on August 2013, the consolidated numbers of CY2013 include the revenues and profits of the Infusion business, further as the company now moves to a Financial Year reporting, this year's results includes a 15 month period, hence the previous year and this year results are not comparable.

(Values in Rupees Mn)

Particulars	Q1CY15	Q1CY14	Growth	Q4CY14	Year to Date (15 months)	**CY2013
Net Income	*1,579	*1,368	15%	*1,826	*7,998	6,678
EBITDA	@373	@381	-2%	733	2,418	2,100
EBITDA%	24%	28%		40%	30%	31%
PAT	@104	@133	-22%	#898	#1495	844
PAT%	7%	10%		49%	19%	13%

\* Includes pass through sales of Claris Otsuka

\*\* Includes the Infusion Business transferred to Claris Otsuka

# PAT of Q4CY14 includes a onetime reversal of differed tax liability of Rs. 518 mn due to the slump sale to CIL

@ EBITDA and PAT have fallen as compared to the same quarter previous year, due to drop in other income of treasury funds.

**REVENUE**

- The Total Revenue for the quarter grew by 15% over the same quarter last year.
- As the pass through sales of Claris Otsuka reduces the revenue will continue to go down, but this would positively affect the margins of the business going forward.

**EBITDA**

- The EBITDA for the quarter fell by 2% over the same quarter last year, due to reduce other income of around 5 Cr from the treasury operation. In Q1CY14 the funds generating income were higher by Rs. 300 Cr as the company as the company had the funds allocated for buyback in the treasury..
- The EBITDA margin for the 15 months of this year financials was in line with the CY2013 at 30% against 31%.
- The EBITDA margins for Q1CY15 stood at 24% as compared to 28% in the same quarter previous year.

**PAT**

- The PAT fell by 22% over the same quarter last year, due to reduced income of around 5 Cr from the treasury operation. In Q1CY14 the funds generating income were higher by Rs. 300 Cr as the company had the funds allocated for buyback in the treasury.



- Year on Year pat is not comparable due to the 15 month financial year, the PAT margins of this financial year (15 months) were higher at 19% than the 13% margins of CY2013.
- The PAT margins for Q1CY15 stood at 7%.

#### **Other Updates:**

##### *Para IV Settlement with Fresenius:*

- On 2th of April 2015, the Company had reached a settlement and license agreement, ending all pending litigation with Fresenius Kabi USA, Inc. with reference to the alleged infringement of a patent relating to Propofol for Injection, 10 mg/ml, which is a generic version of DIPRIVAN.
- Under the terms of the Settlement and License Agreement, Claris and Claris Lifesciences Inc. (USA) has been granted approval to sell its generic version of Propofol for Injection beginning 15th October 2016, prior to the 1st June 2025 expiry of the patent that formed the basis of the litigation.
- According to IMS health data as of June 2014, Propofol Injection had an annual market size of approximately US\$ 251 million in the USA.

##### *Regulatory updates:*

- The US is the most important region and the Company has filed at total of 39 ANDAs in the US, out of which 13 ANDAs have been approved and another 26 are under approval. The total addressable market size of the 39 ANDAs is approximately US\$ 2,000 million, out of which the market size of approved ANDAs and under approval ANDAs stood at approximately US\$ 200 million and US\$ 1,800 million respectively.
- During the quarter, the company received approval of a supplementary ANDA, for Fluconazole in 100 and 200 ml Non PVC Bags, in the USA.
- The company has filed for 1 ANDA during this quarter, and plans to file 18 ANDAs in the US during FY2016; this is in line with the company's target to have a total of 100 ANDAs in the US by 2018-19.

##### *Capacity Expansion & Technology Up-gradation:*

- The company invested in a new plant Clarion 2 with terminally sterile, aseptic and lyophilized capabilities.
- The second line has been installed and has commenced sales in EMs from this second line.



- The packaging automation at the Plant 1 is underway for the SVP and Propofol lines; this will result into an online packaging process as well with limited human intervention as preferred by regulatory authorities and also strive towards higher levels of quality and compliance.
- In line with the Good Manufacturing Practices (GMP), the company is investing in new and revamping the existing software, Chromeleon, LIMS, Trackwise and Training Management Systems will be incorporated at the manufacturing facilities that will again strive towards higher levels of quality and compliance.

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#### Disclaimer

This press release may include "forward-looking statements" which involve a number of risks, uncertainties and other factors that may cause actual results to differ materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategy, the market acceptance of and demand for our products, our growth and expansion, technological change and our exposure to market risks. By their nature, these expectations and projections are only estimates and could be materially different from actual results in the future. Claris Lifesciences Limited does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof. Market information mentioned in the press release is based on IMS Data and/or internal estimates of the company. The press release also contains the carved out financials of the business transferred to Claris Injectables Limited (CIL), these carved out business are management representations and are not audited numbers.

#### About Claris Lifesciences Limited (CLL)

Claris Lifesciences Limited (BSE Code: 533288) the Company with three segmental revenues, (i) the Speciality Injectables Business which is housed in a wholly owned subsidiary; Claris Injectables Limited, (ii) 20% stake in the Joint Venture with Otsuka and Mitsui for the Infusion Business in India and Emerging Markets, and (iii) the Treasury and Cash management for the funds in the HoldCo.

For more information about the company, log on to: [www.clarislifesciences.com](http://www.clarislifesciences.com)

#### About Claris Injectables Limited (CIL)

Claris Injectables Limited is one of the largest sterile injectables pharmaceutical companies in India. The company manufactures and/or markets products across various therapeutic segments including Anesthesia, Plasma Volume Expanders, Blood Products, Parenteral, Infusion therapy, Anti-infective and Renal Care. A significant majority of these products are generic drugs that are capable of being directly injected into the human body and are predominantly used in the treatment of critical illnesses.

The company has 3 manufacturing plants; at its campus on the out skirts of Ahmedabad. With emphasis on Quality, Technology & Innovation, Claris offers a range of niche technology-driven injectable products across delivery systems such as glass bottles, glass vials & ampoules, and non-PVC/PVC bags. Claris' sterile injectables facilities have been approved by regulatory authorities including USFDA, MHRA (UK), TGA (Australia), and GCC FDCA. The company's manufacturing capabilities have several times received awards from prestigious institutions like Frost & Sullivan and IDMA.

For more information about the company, log on to: [www.clarisinj.com](http://www.clarisinj.com)

#### About Claris Otsuka Private Limited (COL)

Claris Otsuka Private Ltd. (Claris Otsuka) is a Joint Venture between Claris Lifesciences Ltd., India, Otsuka Pharmaceutical Factory, Inc., Japan and Mitsui & Co. Ltd., Japan, for Claris' Infusion Business in India and Emerging Markets. The company primarily manufacture & market products across multiple markets and therapeutic segments. Claris Otsuka, a leader in intravenous nutrition products, is committed to being the best partner of patients and healthcare professionals in the field of clinical nutrition.

The company has products ranging across various therapeutic segments, including infusion therapy, parenteral nutrition, anti-infectives, and plasma volume expanders. We offer injectables in various delivery systems, such as glass and plastic bottles (EURO Head & Nipple Head), ampoules, and non-PVC/PVC bags.

The company's customer base primarily includes government and private hospitals, aid agencies, and nursing homes.

The company has two state-of-the-art plants at our manufacturing facility located in Ahmedabad, India. One of the facilities has been approved by foreign regulatory authorities including ANVISA (Brasil).

For more information about the company, log on to: [www.clarisotsuka.com](http://www.clarisotsuka.com)